

PATENT APPLN. NO. 10/593,483  
RESPONSE UNDER 37 C.F.R. §1.111

**PATENT  
NON-FINAL**

REMARKS

Claim 1 has been amended to include the limitations of claims 3-5. I.e., claim 1 has been amended to define the bypass communication passage as including a circumferential groove formed in an approximately circumferential direction of a base end side of the seal part and a connection passage connecting the circumferential groove and the rear chamber, the connection passage being a spiral groove formed in an outer wall of the intermediate gasket.

Claim 1 has also been amended to define that a powdery medicine is accommodated in the front chamber and a liquid medicine is accommodated in the rear chamber of the barrel of the pre-filled syringe of the present invention. This amendment is supported in paragraph [0060] of the specification of the present application as published (U.S. Patent Application Publication No. 2008/0234632).

Claims 3-8 have been canceled.

Claim 9 has been amended to correct the limitation " $A + B + C < D$ " to " $A + B + C > D$ " for consistency with the descriptions in the specification and amended Fig. 5.

Referring to the Action, the 35 U.S.C. § 102 rejection of claims 1 and 9-11 as being anticipated by Tanaka et al., US 2004/0236273 A1 ("Tanaka"), has been overcome by the amendments to

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claims 1 and 9. Claim 1 as amended includes the limitations of claims 3-5. Claims 3-5 are not included in the 35 U.S.C. § 102 rejection based on Tanaka. It is also noted that Tanaka does not anticipate the further limitations recited in claim 9 as amended. As noted in section 6, pages 4 and 5, of the Action, in Tanaka  $A + B + C < D$  (where A, B, C and D are as defined in the Action).

The 35 U.S.C. § 103(a) rejection of claims 3, 4, 7 and 9 are also overcome by the amendment to claim 1 to include the limitations of claim 5. Claim 5 is not included in the rejection.

The 35 U.S.C. § 103(a) rejections of claims 6 and 8 have been rendered moot by the cancellation of these claims.

The only rejection remaining in the Action that is relevant to the claims as amended in the 35 U.S.C. § 103(a) rejection of claim 5 as being unpatentable over Tanaka/Higashikawa (U.S. Pat 5,830,193) in view of Grimard et al., U.S. Pat 5,899,881 ("Grimard").

The rejection of claim 5, as it applies to claim 1 as now amended, is not proper because the proposed modification of the syringe of Tanaka, as modified by Higashikawa as proposed in the Action, to include the spiral groove of the intermediate gasket of Grimard will not result in the pre-filled syringe of the present invention.

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In the pre-filled syringe of the present invention as recited in the amended claims, the intermediate gasket has a spiral groove provided on the base end side of the gasket. By means of the spiral groove provided on the base end side of the gasket, the operation of providing communication between the front chamber and the rear chamber can be carefully performed. That is, when the plunger rod is pushed, liquid flows in the spiral groove. Time is required for the liquid to reach the circumferential groove of the bypass communication passage and the intermediate gasket is prevented from significant forward movement during this operation.

It is generally difficult for a person operating a pre-filled syringe to immediately control the pushing power of the plunger rod. The pre-filled syringe of the present invention having the spiral groove on the base end side of the intermediate gasket allows for the pushing power to be controlled before the intermediate gasket begins to move forward. In addition, communication between the chambers can be confirmed from anywhere on the periphery of the syringe.

On the other hand, the helical groove of the intermediate gasket of Grimard is required to be provided on the front end side of the gasket for the purpose of providing a swirling action of the diluent "D" entering the medicament chamber (Col. 10, line 28 et

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seq of Grimard).

At best, Grimard suggests providing a helical groove on the front end side of the intermediate gasket of Tanaka/Higashikawa. Such modification of the pre-filled syringe of Tanaka/Higashikawa will not result in the pre-filled syringe of the present invention.


For the above reasons, the combination of Tanaka/Higashikawa fails to support a case of prima facie obviousness under 35 U.S.C. § 103(a) of original claim 5 of the application and the claims of the application as currently amended.

Removal of the rejections of the claims of the application and a notice of allowability of the application are believed to be in order and are respectfully requested.

The foregoing is believed to be a complete and proper response to the Office Action dated February 22, 2010.

In the event that this paper is not considered to be timely filed, applicant hereby petitions for an appropriate extension of time. The fee for any such extension and any additional required fees may be charged to our Deposit Account No. 111833.

Respectfully submitted,  
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